RENONLAB 南通理能实验器材有限公司
NANTONG RENON LABORATORY EQUIPMENT CO., LTD

Date of issue: **January 1st, 2016**
Our. ref. Nr. 2016-MD-Eco/03
Object: **distribution letter for tenders**

To whom it may concern

The company
NANTONG RENON LABORATORY EQUIPMENT CO.,LTD
NO.128 XIAOHAI ROAD, SANHE TOWN, HAIMEN CITY, JIANGSU PROVINCE, CHINA
TEL:86(513)82233576
declares that this letter acknowledges that

"ECOCHIMIE" S.R.L.
5/1, I. Cuza-Voda bvd., MD2060, Chisinau
Republic of Moldova
Tel.: +/373/22 523432
Fax: +/373/30 523422
E-mail: import@ecochimie.md

is our authorized distributor for the complete NANTONG RENON LABORATORY EQUIPMENT CO.,LTD product line.

This company is able to provide competitive and professional sales information, to take parts in tenders and after-sales service of NANTONG RENON LABORATORY EQUIPMENT CO.,LTD products to their customers in his area and to participate in tenders on behalf of NANTONG RENON LABORATORY EQUIPMENT CO.,LTD

President

NANTONG RENON LABORATORY EQUIPMENT CO.,LTD
Signature and seal

南通理能实验器材有限公司
NANTONG RENON LABORATORY EQUIPMENT CO.,LTD

Authorized Signature(s)

地址：江苏省海门市三和镇小海路128号
ADDRESS: NO.128, XIAOHAI ROAD SANHE TOWN, HAIMEN CITY, JIANGSU PROVINCE, CHINA
TEL: 86(513)82233576 FAX: 86(513)82305748 E-mail: renonlab@yahoo.com.cn

nqa.

CE Compliance Report

Applicant: NANTONG RENON LABORATORY EQUIPMENT CO., LTD
Address: NO128, XIAOHAI ROAD, SANHE TOWN, HAIMEN CITY, JIANGSU PROVINCE, CHINA
Product: Pipette Tips, Centrifuge Tube, Cryotube, Reagent Bottle, Test Tube, Test Tube Stopper, Plastic Rack, Plastic Box, Embedding Cassettes, Transfer Pipette, Urine Cup, Stool Cup, Sample Cup, Colorimetric Cup, Cuvette, Petri Dish, Cell Culture Plate, Cell Culture Bottle, Loops, Swab Pads, Slides , Cover Glass, Pipette, Blood Collection Tube, Capillary Tube, Sample Swab Tube, Tweezers, Brush, ESR Tube, ESR Rack, Plastic Speculum, Centrifuge, Plastic Clamp, Glassware, Plastic Needle Sampling, Sample Box, Sample Bag, Tighten Belt, Centrifugal Rack, Slide Staining Rack, Slide Staining Jar, Slide Mailer
Type: See Annex of details
Product Classification: Other

The submitted technical files including test report of the above products have been reviewed against the self declaration requirements of conformity for CE marking according to Annex II & III of the 98/79/EC In Vitro Diagnostic Medical Devices Directive.
The review result of the technical files and test report support the self declaration for the devices listed above. The test report and the technical files are the annex of this report and should be used together.

Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) have been complied to be met.
This report is not a certificate of conformity.
No. **02747**
Initial Issue Date: **24 July 2017**

Tony Chen
General Manager (Signature)

Annex to Report (No. 02747)

NANTONG RENON LABORATORY EQUIPMENT CO., LTD

Product Name	Type
Pipette Tips	10ul, 100ul, 200ul, 300ul, 500ul, 1ml, 5ml, 10ml
Centrifuge Tube	0.2ml, 0.5ml, 1ml, 1.5ml, 2ml, 5ml, 7ml, 10ml, 15ml, 50ml,100ml
Cryotube	0.5ml, 1.0ml, 1.5ml, 1.8ml, 2ml, 4ml, 5ml, 7ml, 10ml
Reagent Bottle	1ml, 2ml, 5ml, 10ml, 20ml, 50ml, 100ml, 500ml
Test Tube	PS test tube, PP test tube, Glass test tube, Screw test tube 12*60, 12*75, 13*75, 12*100, 13*100, 15*100, 16*100, 18*100,18*150
Test Tube Stopper	Φ12mm, 13mm, 15mm, 16mm
Plastic Rack	Test tube rack, pipette rack, centrifuge tube rack
Plastic Box	TIPS BOX, CENTRIFUGE TUBE BOX, CRYO BOX
Embedding Cassettes	Square hole, Stripe hole, Round hole
Transfer Pipette	0.5ML, 1ML, 2ML, 3ML, 5ML, 10ML
Urine Cup	5ml, 10ml, 15ml, 20ml, 25ml, 30ml, 40ml, 50ml, 60ml, 80ml, 90ml, 100ml, 120ml, 150ml
Stool Cup	5ml, 10ml, 15ml, 20ml, 25ml, 30ml, 40ml, 50ml, 60ml, 80ml, 90ml, 100ml, 120ml, 150ml
Sample Cup	SPB1~SPB17
Colorimetric Cup	SPA1~SPA27
Cuvette	CV1~CV13

This annex is only valid if attached to the report mentioned above.

Annex to Report (No. 02747)

NANTONG RENON LABORATORY EQUIPMENT CO., LTD

Product Name	Type
Petri Dish	Φ30MM, 60MM, 90MM, 100MM, 120MM, 150MM
Cell Culture Plate	6 holes, 12holes, 24holes, 48holes, 96 holes V bottom, U bottom, Flat bottom
Cell Culture Bottle	25ml, 50ml, 250ml, 600ml
Capillary Tube	Blue type, Red type, EDTA type
Loops	1ul, 10ul, 1ul/10ul double use
Swab Pads	50*50MM, 60*60MM, 43*43MM, 50*50MM
Slides	7101, 7102, 7105, 7107, 7109
Cover Glass	18*18mm, 20*20mm, 22*22mm, 22*32mm, 24*24mm, 24*32mm, 24*50mm, 22*60mm, 24*60mm
Pipette	Adjustable, fixed
Blood Collection Tube	Vacuum blood tube, Non vacuum blood tube
Sample Swab Tube	12*160mm, RED TYPE, BLUE TYPE
Tweezers	Ge-33, GE-34, GE-35
Brush	17 TYPE, 18 TYPE, 19 TYPE
ESR Tube	GLASS ESR TUBE, PLASTIC ESR TUBE
ESR Rack	Plastic, steel
Plastic Speculum	A TYPE, B TYPE, C TYPE

This annex is only valid if attached to the report mentioned above.

This report is the property of NQA and should be returned to NQA upon request.

Annex to Report (No. 02747)

NANTONG RENON LABORATORY EQUIPMENT CO., LTD

Product Name	Type
Centrifuge	0.5ml, 1.5ml, 15ml, 50ml, 800, 801, 802
Plastic Clamp	GE-31, GE -32
Glassware	Beaker, flask, measuring cylinder, measuring cup, Volumetric flask, reagent bottle, funnel, core filter device, dedicator, alcohol lamp, watch glass, petri dish
Plastic Needle Sampling	7, 7-1, 8, 9, 10, 11, 12, 13
Sample Box	PLASTIC SAMPLE BOX, PAPER SAMPLE BOX
Sample Bag	Large, Small
Tighten Belt	A, B, C
Centrifuge Tube Rack	90holes, 60holes, 40holes, 50holes
Slide Staining Rack	24hole, 30hole, 60hole
Slide Staining Jar	5hole, 9hole, 10hole, 30hole, 60hole
Slide Mailer	1HOLE, 2HOLE, 3HOLE, 5HOLE, 10HOLE, 12 HOLE, 20HOLE, 30HOLE, 50HOLE, 100HOLE

This annex is only valid if attached to the report mentioned above.

Certificate of Registration

This is to certify that the Quality Management System of

Nantong Renon Laboratory Equipment Co., Ltd.

Unified Social Credit Code : 91320684687160886X
Operation Address : No.128, Xiaohai Road, Sanhe Town, Haimen City, Nantong City, Jiangsu Province, China
Registered Address : No.128, Xiaohai Road, Sanhe Town, Haimen City, Jiangsu Province, China

applicable to

Production and Sale of Laboratory Plastic Consumables(Pipette Tips, Centrifuge Tube, Cryovial Tube, Test Tube, Tube Stopper, Plastic Rack, Plastic Box, Embedding Cassette, Pipette, Cuvette, Sharp Container, Petri Dish, Microplate, Sample Cup, Specimen Container, Loop Sample Needle, Blood Collection Tube)(Exports to the United States and the European Union); Sales of Glass Slide, Cover Slide, Serological Pipette, Transferpettor, ESR Tube, Cotton Tip, Umbilical Cord Clamp, Swab tube, Cytology Brush(Exports to the United States and the European Union)

has been assessed and registered by NQA against the provisions of

ISO 13485: 2003

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by NQA.
Certified Clients shall accept regular surveillance assessments, the validity of certificates shall be maintained for the positive result of audit.
The information of this certificate can be checked on CNCA's website (www.cnca.gov.cn)
SNQA's website : www.snqa.com.cn

Managing Director

Certificate Number 43827

Date: 01 September 2017
Valid Until: 31 March 2019
EAC Code: 19/14

UKAS MANAGEMENT SYSTEMS 015

DECLARATION OF EC CONFORMITY

WE:

Name of Manufacturer: Limited Liability Company SOLAR
UKRAINE, 36014 Poltava, Ostrovskogo str. 57

EU Representative: PRZEDSIEBIORSTWO Innowacyjno- Handlowe VARIA Ltd.
POLAND, 60-473 Poznan, Biecka str. 10

Hereby declare, that the product:

Name of product: **Recording Thermal Papers**

Product code: Variable. It depends on dimension and format type

Classification
(per rule 1, Annex IX, 93/42/EEC): **Device of class "I"**

conforms to the MDD 93/42/EEC Council Directives

Applied harmonised standards, national
standards or other normative documents: EN ISO 14971:2009, PN- EN ISO 14971:2009, EN 980:2008, PN-EN 980: 2008, EN 1041:2008, PN-EN 1041:20120

Conformity assessment procedure: Annex VII point 3 of MDD 93/42/EEC Directive

Technical files at competent authority disposal

The director
Mrs. Diachenko Olena

Poltava, 01-06-2012

ООО «Солар»	
Украина, 36014, г. Полтава	р/р 26007210339153 в АО "ПроКредит Банк"
ул. Островского, 57	МФО 331489; Код ЕГРПОУ 32544823
Тел: (0532) 61-06-47	

Сертификат качества №25

на ленту диаграммную рулонную и складывающуюся, производитель ООО «Солар» Украина, г. Полтава

Название продукции	Описание товара	Количество рулонов и пачек, (шт.)	Масса нетто, партии, (кг)	Дата изготовления
Лента диаграммная для регистр. приборов	бумажные рулоны и пачки с нанесением диаграммы	11663	1323	март 2017 г.

Основные характеристики продукции

Название продукции	Размер ленты	Плотность, г/м2	Кол-во пачек в упаковке	Кол-во упаковок
Лента диаграммная для регистрирующих приборов в рулонах и пачках	50х25х12 пар	55	110	4
	50х30х16 пл	55	100	1
	50х50х18 пл	55	70	1
	57х18х12 пар	55	120	2
	57х20х12 пар	55	120	20
	57х30х12 пар	55	90	1
	58х25х12 пар	55	110	1
	60х10х12 пар	55	150	4
	60х15х16 пар	55	120	3
	60х30х16 пар	55	70	2
	63х30х16 пл	55	70	4
	80х20х12 пар	55	80	12
	80х20х16 пл	55	80	1
	80х25х12 пар	55	60	3
	80х30х12 пар	55	60	50
	90х28х19 пар	55	50	2
	90х50х18 пл	55	30	1
	110х10х12 пар	55	100	1
	110х20х16 пл	55	60	1
	110х25х12 пар	55	60	2
	110х25х12 пар	55	60	5
	110х30х12 пар	55	60	1
	112х10х12 пар	55	100	1
	112х25х12 пар	55	60	2
	112х30х12 пар	55	60	4
	120х28х19 пар М	55	50	1
	144х30х16 пл	55	40	3
	145х30х16 пл	55	40	2
	210х20х16 пл	55	35	6
	210х30х18 пл	55	25	8
	210х30х19 пар	55	25	1
	215х20х16 пар	55	35	1
	216х30х15 пл	55	25	23
	104х100х300	55	54	1
	110х140х140	55	72	4
	110х140х150	55	72	2
	110х140х200	70	40	1
	230х280х180	55	12	8
	340х300х200	55	8	2

Основные характеристики бумаги, из которой изготовлена продукция

Название продукции	Основные параметры бумаги				
	Масса 1 м²	Гладкость	Белизна	Разрывная сила Н/м²	
				Вдоль	Поперек
Лента диаграммная	55	400	92	40	20
	70	400	92	51	29

Декларация заявителя

Нижеподписавшийся заявляет, что вышеприведенные данные соответствуют действительности, что вся лента диаграммная полностью изготовлена или в достаточной мере переработана в Украине и что она соответствует требованиям ГОСТ 7826-93, установленным в отношении таких товаров.

Директор _____ **Е.И. Диченко**

03 марта 2017г. М.П.

Zhejiang Sorfa Medical Plastic CO., Ltd

To Whom It May Concern:

Date: 24-April, 2014

Zhejiang Sorfa Medical Plastic Co., Ltd,
No.148 Longshan Road, Zhongguan Town, Deqing, Zhejiang, China

Here by certify that

SRL Ecochimie
Off. 403, 5/1 Cuza Voda bd.
Chisinau, MD-2060
Republic of Moldova

Is our authorized exclusive distributor for the entire territory of Moldova to promote and sell the whol range of Sorfa Laboratory Consumable products.

This Certificate is valid until April 23th, 2019.

For An On behalf of Sorfa Medical Plastic.

Yours Sincerely,

John Jiang

General Manager

No. 148 Longshan Road, Zhongguan Town, Deqing, Zhejiang, China
Tel: 86-572-8408068 Fax: 86-572-8408000 Email: info@sorfa.com

Compliance Report

Applicant:	Zhejiang Sorfa Life Science Research Co., Ltd.
Address:	148 Longshan Road, Zhongguan Town, Deqing 313220, Zhejiang, China.
Product:	Cryogenic Vials, 2D Barcode Cryogenic Vial, Freezing Tube, Plastic Cryogenic Storage Boxes, Color Code, Centrifuge Tubes, Plastic Rack, Cell Strainer, Micro Tube, PCR Tube, Cell Culture Flask, Cell Culture Plate, Cell Culture Dish, Petri Dish, Standard Serological Pipette, Stretching Serological Pipette, Short Serological Pipette, Without Tip Serological Pipette, Aspirating Pipette, Colorized Serological Pipette, Graduated Bacterial Pipette, Cell Culture Pipette, Large Volume Pipette, Pipette Tip, Cell Scraper, Cell Spreaders, Inoculating Loop, Inoculating Needles, Vacuum Filter System, Bottle Top Filter, Solution Bottle, Syringe Filter, Blender bag, Sterile Sampling Bag, Media Bottle, Effervescent Tablet Tubes, Reagent Bottle, Dropper Bottle, FOB Bottle, ESR Pipette, ESR Rack, Diagnostic Cassette, Specimen Container, Transfer Pipette
Type:	See annex for details
Product Classification:	Others

The submitted technical files including test report of the above products have been reviewed against the self declaration requirements of conformity for CE marking according to Annex II & III of the 98/79/EC In Vitro Diagnostic Medical Devices Directive.

The review result of the technical files and test report support the self declaration for the devices listed above. The test report and the technical files are the annex of this report and should be used together.

Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) have and continue to be met.
This report is not a certificate of conformity.

No. **02552**
Initial Issue Date: **15 Nov 2016**

Tony Chen

General Manager (Signature)

Annex to Report (No. 02552)

Zhejiang Sorfa Life Science Research Co., Ltd.

Product Name	Type
Cryogenic Vials	T101, T102, T114, T115, T131, T132, T133, T134, T135,T136, T137, T138, T139, T2051, T2052, T2053, T2054, T2201, T2202, T2203, T2204
2D Barcode Cryogenic Vial	T2051, T2052, T2053, T2054, T2055, T2016, T2201, T2202, T2203, T2204, T2205, T2206
Freezing Tube	T118, T119, T105, T105-2, T105-3
Plastic Cryogenic Storage Boxes	T130-2, T130-3, T142, T142-1, T142-2, T142-3, T130-1, T145-1, T145-2, T145-3, T145-4, T146, T3051, T3052
Color Code	T144
Centrifuge Tubes	T121-1, T121-2, T121-3, T121-4, T121-5, T121-6, T124-1, T124-2, T124-3, T124-4, T124-5, T124-6, T125-1, T125-2, T125-3, T125-4, T126
Plastic Rack	T127, T128
Cell Strainer	SCS401, SCS701, SCS1001, SCS402, SCS702, SCS1002
Micro Tube	T004-1, T006-1, T008-1, T020-1
PCR Tube	T002-1, T003-1, T016-1
Cell Culture Flask	SCF11050, SCF12050, SCF01050, SCF02050, SCF11250, SCF12250, SCF01250, SCF02250, SCF11600, SCF12600, SCF01600, SCF02600
Cell Culture Plate	SCP11006, SCP01006, SCP10006, SCP00006, SCP11012, SCP01012, SCP10012, SCP00012, SCP11024, SCP01024, SCP10024, SCP00024, SCP11096, SCP01096, SCP10096, SCP00096
Cell Culture Dish	SCD11135, SCD10035, SCD11060, SCD10050, SCD11100, SCD10100, SCD11150, SCD10150
Petri Dish	SPD11035, SPD11060, SPD11100, SPD11101, SPD11061, SPD11150
Standard Serological Pipette	P8010, P8012, P8020, P8022, P8050, P8052, P8100, P8102, P8250, P8252, P8500, P8502, P81000, P81002
Stretching Serological Pipette	P8050-3, P8052-3, P8100-3, P8102-3, P8150-3, P8152-3
Short Serological Pipette	P8010-5, P8012-5, P8020-5, P8022-5, P8050-5, P8052-5, P8100-5, P8102-5, P8250-5, P8252-5

This annex is only valid if attached to the report mentioned above

Annex to Report (No. 02552)

Zhejiang Sorfa Life Science Research Co., Ltd.

Product Name	Type
Without Tip Serological Pipette	P8010-4, P8012-4, P8020-4, P8022-4, P8050-4, P8052-4, P8100-4, P8102-4
Aspirating Pipette	P8010-1, P8012-1, P8020-1, P8022-1, P8050-1, P8052-1, P8100-1, P8102-1, P8250-1, P8252-1, P8500-1, P8502-1, P81000-1, P81002-1
Colorized Serological Pipette	P8010-6, P8012-6, P8020-6, P8022-6, P8050-6, P8052-6, P8100-6, P8102-6, P8250-6, P252-6
Graduated Bacterial Pipette	P8310, P8312, P8320, P8322
Cell Culture Pipette	P8410, P8412, P8420, P8422
Large Volume Pipette	PP0020, P0100, P0250, P1000, P2000
Pipette Tip	P900101, P900102, P900103, P900104, P900105, P900106, P900107, P900108, P900109, P900110, P901001, P901002, P901003, P901004, P901005, P902001, P902002, P902003, P902004, P902005, P903001, P903002, P903003, P903004, P903005, P910001, P910002, P910003, P910004, P910005, P912501, P912502, P912503, P912504, P912505
Cell Scraper	SC010, SC011, SC020, SC021
Cell Spreaders	SC110, SC111, SC115, SC116, SC030, SC031, SC040, SC041
Inoculating Loop	L10301S, L10310S, L10401S, L10410S
Inoculating Needles	L10201S, L10210S
Vacuum Filter System	SPE22150, SPE45150, SMC22150, SMC45150, SPV22150, SPV45150, SNY22150, SNY45150, SPE22250, SPE45250, SMC22250, SMC45250, SPV22250, SPV45250, SNY22250, SNY45250, SPE22500, SPE45500, SMC22500, SMC45500, SPV22500, SPV45500, SNY22500, SNY45500, SPE22000, SPE45000, SMC22000, SMC45000, SPV22000, SPV45000, SNY22000, SNY45000

This annex is only valid if attached to the report mentioned above.

Annex to Report (No. 02552)

Zhejiang Sorfa Life Science Research Co., Ltd.

Product Name	Type
Bottle Top Filter	SPE22150S, SPE45150S, SMC22150S, SMC45150S, SPV22150S, SPV45150S, SNY22150S, SNY45150S, SPE22250S, SPE45250S, SMC22250S, SMC45250S, SPV22250S, SPV45250S, SNY22250S, SNY45250S, SPE22500S, SPE45500S, SMC22500S, SMC45500S, SPV22500S, SPV45500S, SNY22500S, SNY45500S, SPE22000S, SPE45000S, SMC22000S, SMC45000S, SPV22000S, SPV45000S, SNY22000S, SNY45000S
Solution Bottle	STF10150, STF10250, STF10500, STF101000
Syringe Filter	SPE22015, SPE45015, SPE22030, SPE45030, SMC22015, SMC45015, SMC22030, SMC45030, SPV22015, SPV45015, SPV22030, SPV45030, SNY22015, SNY45015, SNY22030, SNY45030, SPT22015, SPT45015, SPT22030, SPT45030
Sterile Sampling Bag	SOR1750, SOR1751, SOR1760, SOR1761, SOR1770, SOR1771, SOR1780, SOR1790, SOR1800, SOR1801, SOR1810, SOR1910, SOR1911, SOR1860, SOR1861, SOR1870, SOR1871, SOR1880, SOR1930, SOR1931, SOR1951, SOR1960
Media Bottle	R3150, R3250, R3500, R31000
Effervescent Tablet Tubes	B501, B502, B503
Reagent Bottle	R501, R502, R503, R504, R505, R506, R507, R115, R119, R109-1, R110-1, R116.1, R109.2, R110-2, R116-2, R109-3, R110-3, R116-3
Dropper Bottle	D301-1, D301-2, D301-3, D301-4, D301-5, D302-1, D302-2, D302-3, D302-4, D302-5, D306-1, D306-2, D306-3, D307-1, D307-2, D307-3, D308-1, D308-2, D308-3, D308-4, D308-5, D308-6, D311-1, D311-2, D311-3, D311-4, D311-5, D311-6, D311-7, D311-8, D311-9, D311-10, D311-11, D311-12, D311-13, D311-14, D311-15, D305-1, D305-2, D305-3, D305-4, D305-5, D305-6, D312-1, D312-2, D312-3, D312-4, D312-5, D313-1, D313-2, D313-3, D313-4, D313-5, D315-1, D315-2, D315-3, D315-4, D315-5, D314-1, D314-2, D314-3, D314-4, D314-5, D314-6, D314-7, D314-8

This annex is only valid if attached to the report mentioned above.

This report is the property of NQA and should be returned to NQA upon request.

nqa.

Annex to Report (No. 02552)

Zhejiang Sorfa Life Science Research Co., Ltd.

Product Name	Type
FOB Bottle	A101-1, A101-2, A101-3, A101-4, A102-1, A204-1, A205-1, A205-2, A206-1, 206-2, A209-1, A209-2
ESR Pipette	L601, L602, L603, L604
ESR Rack	L610
Diagnostic Cassette	W101, W102, W103, W104, W105, W106, W107, W108
Specimen Container	B301, B302, B303, B304, B305
Blender Bag	SOR2071, SOR2072, SOR2031, SOR2061, SOR2011, SOR2012, SOR2013, SOR2021, SOR2022, SOR2023, SOR2041, SOR2043, SOR2051
Transfer Pipette	P101, P102, P103, P104, P105, P106, P107, P108, P109, P110, P111, P112, P113, P114, P115, P116, P117, P118, P119, P120, P121, P122, P123, P124, P125, P126, P201, P202, P203, P204, P205, P206, P207, P208, P209, P210, P211, P212, P213, P214, P301, P302, P303, P304, P305, P306, P307, P308, P401, P402, P403, P404, P405, P406, P407, P408, P501, P502, P503, P504, P505, P701, P702, P703, P704, P705, P706, P602, P604, P605, C101, C102, C103, E101, E102, E103, E104

This annex is only valid if attached to the report mentioned above.

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Zhejiang Sorfa Life Science Research Co., Ltd.
Longshan Road 148#
Zhongguan Town, Deqing County
Huzhou City
313220 Zhejiang
China

has established and applies a quality management system for medical devices for the following scope:

Manufacture and Distribution of Disposable Labwares and Instruments in Medical Use, Cell Scrapers

Proof has been furnished that the requirements specified in

EN ISO 13485:2012
EN ISO 13485:2012/AC:2012

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2016-02-06
Certificate Registration No.:	SX 60107766 0001
An audit was performed, Report No.:	15091959 001
This Certificate is valid until:	2019-02-05

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date 2016-02-06

X. Ren

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60107765 0001

Report No.: 15091959 001

Manufacturer:

Zhejiang Sorfa Life Science
Research Co., Ltd.
Longshan Road 148#
Zhongguan Town, Deqing County
Huzhou City
313220 Zhejiang
China

Products:

Aspects of manufacture concerned with securing and maintaining sterile conditions of Cell Scrapers

Replaces Approval, Registration No.: DD 60041680 0001

Expiry Date: 2021-02-05

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2016-02-06

Date: 2016-02-06

Notified Body TÜV Rheinland LGA Products GmbH
X. Ren
Zertifizierungsstelle

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

STANCHEM Sp. z o.o.
PRZEDSIĘBIORSTWO CHEMICZNE

ЛЮБЛИН, 29.12.2017

ДОВЕРЕННОСТЬ ОТ ПОСТАВЩИКА

Stanchem Sp. z o.o. Przedsiębiorstwo Chemiczne доверяет SRL „Ecochimie", Молдова, Кишинев, ул. Валя Кручий 2\85 продажу химреактивов закупаемых в нашей компнии для реализации их на территории Респуюблики Молдова и представлять нашу продукцию с правом реализации в открытых конкурсах, тендерах по государственным закупкам для Санитарно-Эпидемиологических Центров, медицинских и других государственных учреждений.

Качество химреактивов гарантировано сертификатами качества производителя.

С уважением
Коммерческий Директор
Marcin Wozniak

STANCHEM Sp. z o.o.
Przedsiębiorstwo Chemiczne
20-481 Lublin, ul. Olszewskiego 12
REGON 430843091 NIP 946 19 56
Biuro Handlowe i Magazyn
21-025 Niemce, ul. Kolejowa 1
tel. 81 718-64-00, fax 81 718-64-
-1-

Ul. K. OLSZEWSKIEGO 12, 20-481 LUBLIN • POLAND
Biuro Handlowe i Magazyn: ul. Kolejowa 105 A, 21-025 Niemce
Tel. +48 81 718-64-00 lub 15 • Fax +48 81 718-64-05
E-mail: office@stanchem.pl • www.stanchem.pl
NIP 946-19-56-540 • REGON 430843091
Sąd Rejonowy w Lublinie VI Wydział Gospodarczy KRS Nr 0000036331
Kapitał zakładowy 10.000.000 PLN
Rok założenia 1997

Lloyd's Register
LRQA

CERTYFIKAT ZATWIERDZENIA

Zaświadcza się, że System Zarządzania Jakością Przedsiębiorstwa:

STANCHEM Sp. z o.o.
Przedsiębiorstwo Chemiczne
ul. Kolejowa 105A, 21-025 Niemce

został zatwierdzony przez Lloyd's Register Quality Assurance
jako zgodny z następującymi normami zarządzania jakością:

ISO 9001:2015

System Zarządzania Jakością obejmuje:

Handel krajowy i zagraniczny metalami, żelazostopami, stopami metali, surowcami i odczynnikami chemicznymi oraz wyrobami stalowymi. Magazynowanie i prowadzenie składu celnego na terenie przedsiębiorstwa.

Nr Certyfikatu
Zatwierdzenia:
GDK0003448

Data zatwierdzenia po raz pierwszy:	18 grudnia 2002
Data wydania niniejszego certyfikatu:	4 stycznia 2018
Data ważności niniejszego certyfikatu:	31 grudnia 2020

Wystawiony przez: Lloyd's Register (Polska) sp. z o.o.
w imieniu Lloyd's Register Quality Assurance Limited

UKAS
MANAGEMENT
SYSTEMS
001

Lloyd's Register (Polska) sp. z o.o., Al. Zwycięstwa 13a, 80-219 Gdańsk, KRS 0000117768
w imieniu LRQA Ltd 1 Trinity Park, Bickenhill Lane, Birmingham, B37 7ES, United Kingdom

Lloyd's Register
LRQA

CERTIFICATE OF APPROVAL

This is to certify that the Quality Management System of:

STANCHEM Sp. z o.o.
Przedsiębiorstwo Chemiczne
ul. Kolejowa 105A, 21-025 Niemce, Poland

has been approved by Lloyd's Register Quality Assurance
to the following Quality Management System Standards:

ISO 9001:2015

The Quality Management System is applicable to:

Foreign and domestic trade of metals, ferroalloys, metal alloys, chemical raw materials and pure chemicals and steel products. Storage and custom warehouse at company premises.

Approval
Certificate No:
GDK0003448

Original Approval:	18th December 2002
Current Certificate:	4th January 2018
Certificate Expiry:	31st December 2020

Issued by: Lloyd's Register (Polska) sp. z o.o.
for and on behalf of Lloyd's Register Quality Assurance Limited

UKAS
MANAGEMENT
SYSTEMS
001

QSCert

We cover credibility

QSCert, spol. s r. o.
Certification Body of Management Systems
Residence address: Klimentská 1746/52, Nové Město, 110 00 Prague 1, Czech Republic
Postal address: Strazska cesta 7892, 960 01 Zvolen, Slovak Republic

by this

CERTIFICATE

certifies that the Quality Management System of

PJSC "Steklopribor"

18, Ozerna str., Zavodske, Lokhvytsky district, Poltava region, 37240, Ukraine

has been established and duly implemented and company applies it in accordance with the standard

ISO 9001:2008

provisions for the following areas:

Design, development, production and sales of technical thermometers and accessories thereof, hydrometers, hygrometers, vacuum manometers, domestic thermometers, measuring and laboratory glassware

Certified location: 18, Ozerna str., Zavodske, Lokhvytsky district, Poltava region, 37240, Ukraine

On the basis of certification audit, protocol No. R 037/16/39 it was proven that the management system meets the requirements of the above listed standard.

Certificate No.: Q-5497/16
Initial certification date: 01.12.2004
Date of issue: 15.11.2016
Expiry date: 04.11.2019
Expiry date of certificate is conditioned by successful completion of transition audit according to ISO 9001:2015 until 14.09.2018.

IAF MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT

S 3177

CERTIFICATION BODY QSCert OF MANAGEMENT SYSTEMS

Ing. Marcel Slúch
chief executive

This certificate is valid only if it is published among valid certificates on www.qscert.com

IQNet®

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

CISQ/ICIM SPA has issued an IQNet recognized certificate that the organization:

SYNTESYS S.a.s. di Rinaldo Ruggero e C.

Via G. Galilei, 10/3 - Zona Industriale - I-35037 Selve di Teolo (PD)

has implemented and maintains a

Quality Management System

for the following scope:

Trading of products for laboratory analysis. Design, manufacturing and sale of products for laboratory analysis and sanitary products. Sale agency of instruments, reagents and consumable products for laboratory diagnostic.

which fulfils the requirements of the following standard:

ISO 9001:2015

Issued on:	**2018-06-04**
First issued on:	**2013-06-05**
Expires on:	**2019-06-04**

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document.

Registration Number: IT-83562

IQNet

Alex Steichitoiu
President of IQNET

CISQ

Ing. Claudio Provetti
President of CISQ

IQNet Partners*:
AENOR *Spain* AFNOR Certification *France* APCER *Portugal* CCC *Cyprus* CISQ *Italy*
CQC *China* CQM *China* CQS *Czech Republic* Cro Cert *Croatia* DQS Holding GmbH *Germany* FCAV *Brazil*
FONDONORMA *Venezuela* ICONTEC *Colombia* Inspecta Sertifiointi Oy *Finland* INTECO *Costa Rica*
IRAM *Argentina* IQA *Japan* KFQ *Korea* MIRTEC *Greece* MSZT *Hungary* Nemko AS *Norway* NSAI *Ireland*
NYCE-SIGE *México* PCBC *Poland* Quality Austria *Austria* RR *Russia* SII *Israel* SIQ *Slovenia*
SIRIM QAS International *Malaysia* SQS *Switzerland* SRAC *Romania* TEST St Petersburg *Russia* TSE Turkey YUQS *Serbia*
IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.

* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

0774CM_03_EN

Il presente documento annulla e sostituisce il certificato di pari numero emesso in data 05/06/2016.

ICIM

CISQ is a member of IQNet
THE INTERNATIONAL CERTIFICATION NETWORK
www.iqnet-certification.com

IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

CERTIFICATO n. / *CERTIFICATE No.* 6574/1

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITÀ DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

SYNTESYS S.a.s. di Rinaldo Ruggero e C.

UNITÀ OPERATIVE / *OPERATIVE UNITS*

Via G. Galilei, 10/3 - Zona Industriale - 35037 Selve di Teolo (PD)
Italia

È CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

UNI EN ISO 9001:2015

Sistema di Gestione per la Qualità / *Quality Management System*

PER LE SEGUENTI ATTIVITÀ / *FOR THE FOLLOWING ACTIVITIES*

EA: 29 - 14

Commercializzazione di prodotti per analisi di laboratorio. Progettazione, produzione e vendita di prodotti per analisi di laboratorio e articoli sanitari. Agenzia di vendita di strumentazione, reagenti e materiali di consumo per la diagnostica di laboratorio.

Trading of products for laboratory analysis. Design, manufacturing and sale of products for laboratory analysis and sanitary products. Sale agency of instruments, reagents and consumable products for laboratory diagnostic.

Riferirsi alla documentazione del Sistema di Gestione per la Qualità aziendale per l'applicabilità dei requisiti della norma di riferimento.
Refer to the documentation of the Quality Management System for details of application to reference standard requirements.

Il presente certificato è soggetto al rispetto del documento ICIM "Regolamento per la certificazione dei sistemi di gestione" e al relativo Schema specifico.
The use and the validity of this certificate shall satisfy the requirements of the ICIM document "Rules for the certification of company management systems" and specific Scheme.

Per informazioni puntuali e aggiornate circa eventuali variazioni intervenute nello stato della certificazione di cui al presente certificato, si prega di contattare il n° telefonico +39 02 725341 o indirizzo e-mail info@icim.it.
For timely and updated information about any changes in the certification status referred to in this certificate, please contact the number +39 02 725341 or email address info@icim.it.

Data emissione	Emissione corrente	Data di scadenza
First issue	*Current issue*	*Expiring date*
05/06/2013	04/06/2018	04/06/2019

ICIM S.p.A.
Piazza Don Enrico Mapelli, 75 – 20099 Sesto San Giovanni (MI)
www.icim.it

ACCREDIA
CENTRO ITALIANO DI ACCREDITAMENTO

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

FEDERAZIONE CISQ
www.cisq.com

CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.
CISQ is the Italian Federation of management system Certification Bodies.

0449CM_03_IT

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

CISQ/ICIM SPA has issued an IQNet recognized certificate that the organization:

SYNTESYS S.a.s. di Rinaldo Ruggero e C.

Via G. Galilei, 10/3 - Zona Industriale - I-35037 Selve di Teolo (PD)

has implemented and maintains a

Quality Management System

for the following scope:

Trading of products for laboratory analysis. Design, manufacturing and sale of products for laboratory analysis and sanitary products. Sale agency of instruments, reagents and consumable products for laboratory diagnostic.

which fulfils the requirements of the following standard:

UNI CEI EN ISO 13485:2016

Issued on:	**2018-06-04**
First issued on:	**2014-06-21**
Expires on:	**2019-06-04**

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document.

Registration Number: IT-93779

Alex Stoichitoiu
President of IQNET

Ing. Claudio Proveiti
President of CISQ

IQNet Partners*:
AENOR *Spain* AFNOR Certification *France* APCER *Portugal* CCC *Cyprus* CISQ *Italy*
CQC *China* CQM *China* CQS *Czech Republic* Cro Cert *Croatia* DQS Holding GmbH *Germany* FCAV *Brazil*
FONDONORMA *Venezuela* ICONTEC *Colombia* Inspecta Sertificointi Oy *Finland* INTECO *Costa Rica*
IRAM *Argentina* JQA *Japan* KFQ *Korea* MIRTEC *Greece* MSZT *Hungary* Nemko AS *Norway* NSAI *Ireland*
NYCE-SIGE *México* PCBC *Poland* Quality Austria *Austria* RR *Russia* SII *Israel* SIQ *Slovenia*
SIRIM QAS International *Malaysia* SQS *Switzerland* SRAC *Romania* TEST St Petersburg *Russia* TSE Turkey YUQS *Serbia*
IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.

* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

07740M_03_EN

Il presente documento annulla e sostituisce il certificato di pari numero emesso in data 05/06/2016.

CISQ is a member of IQNet
THE INTERNATIONAL CERTIFICATION NETWORK
www.iqnet-certification.com

IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

ICIM

Certificato N. **7111/1**
Certificate No.

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITÀ DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

SYNTESYS S.a.s. di Rinaldo Ruggero e C.

UNITÀ OPERATIVE / *OPERATIVE UNITS*

Via G. Galilei, 10/3 - Zona Industriale - 35037 Selve di Teolo (PD)
Italia

È CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

UNI CEI EN ISO 13485:2016

Sistema di Gestione per la Qualità / Quality Management System

PER LE SEGUENTI ATTIVITÀ / *FOR THE FOLLOWING ACTIVITIES*

EA: 29 - 14

Commercializzazione di prodotti per analisi di laboratorio. Progettazione, produzione e vendita di prodotti per analisi di laboratorio e articoli sanitari. Agenzia di vendita di strumentazione, reagenti e materiali di consumo per la diagnostica di laboratorio.

Trading of products for laboratory analysis. Design, manufacturing and sale of products for laboratory analysis and sanitary products. Sale agency of instruments, reagents and consumable products for laboratory diagnostic.

Riferirsi alla documentazione del Sistema di Gestione per la Qualità aziendale per l'applicabilità dei requisiti della norma di riferimento.
Refer to the documentation of the Quality Management System for details of application to reference standard requirements.
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The use and the validity of this certificate shall satisfy the requirements of the ICIM document "Rules for the certification of company management systems" and specific Scheme.
Per informazioni puntuali e aggiornate circa eventuali variazioni intervenute nello stato della certificazione di cui al presente certificato, si prega di contattare il n° telefonico +39 02 725341 o inviare e-mail info@icim.it.
For timely and updated information about any changes in the certification status referred to in this certificate, please contact the number +39 02 725341 or email address info@icim.it.

DATA EMISSIONE *FIRST ISSUE*	EMISSIONE CORRENTE *CURRENT ISSUE*	DATA DI SCADENZA *EXPIRING DATE*
21/06/2014	04/06/2018	04/06/2019

ICIM S.p.A.
Piazza Don Enrico Mapelli, 75 - 20099 Sesto San Giovanni (MI)
www.icim.it

ACCREDIA
MEMBRO DEGLI ACCORDI DI MUTUO RICONOSCIMENTO EA, IAF E ILAC
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

FEDERAZIONE CISQ
www.cisq.com
CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.
CISQ is the Italian Federation of management system Certification Bodies.

08560M_02_IT

SYNTESYS

SYNTESYS S.A.S. DI RINALDO R. & C.
VIA G. GALILEI 10/3
35037 Z.I. SELVE DI TEOLO (PD)
TEL. +39 049 9903866 R.A. FAX +39 049 9903867
COD.FISCALE P.IVA N.REG.IMP. PADOVA 03573950288
E-MAIL INFO@SYNTESYS.IT - WEB WWW.SYNTESYS.IT

DICHIARAZIONE DI CONFORMITA'
Conformity declaration

CE

Il sottoscritto, Rinaldo Ruggero legale rappresentante della ditta:
The undersigned, Rinaldo Ruggero legal representative of the company:

produttore/*manufacturer*

SYNTESYS S.a.s. di Rinaldo Ruggero & C.

indirizzo/*address*

Via G. Galilei, 10/3 35037 Zona Industriale SELVE DI TEOLO (PADOVA) ITALY

O rappresentante il mandatario autorizzato entro la Unione Europea or representing the authorized mandatary within the European Community

Mandatario autorizzato/*authorized mandatary*

indirizzo/*address*

Dichiara sotto la propria responsabilità che il prodotto/*declares under his own responsability that the product:*

Denominazione degli articoli prodotti/*Description of Manufacturer*

Contenitori per urina, contenitori per feci, contenitori universali, Pipette Pasteur, Tamponcini cotonati, Tamponi sterili secchi in provetta, tamponi sterili con terreno di traporto, Piastre di Petri, Anse sterili per batteriologia, Aste a "L", Puntali Eppendorf gialli e blue, cuvette per spettrofotometro, tazzine per campionamento siero, bacchette per distacco ed estrazione del coagulo, pinzette in polistirolo monouso, provette monouso in plastica, tappi alettati per provette diam.12 mm e 16mm, provette con granuli ed acceleratore, provette sottovuoto per prelievo, Sistema SEDIPLAST, Microprovette, Portavetrini, Vetrini precolorati, Portaprovette, supporti per microprovette, CELL-VUE- Vetrini monouso per conta spermatozoi, Aghi a farfalla, urinali uomo e donna, padella per ammalati, bottiglia per raccolta urine/

Urine container, faeces container, universal container, Pasteur pipette, Cotton swabs, Sterile swabs in test tubes, sterile swab in test tubes with medium, Petri dishes, Sterile loops, Sterile loops open "L", Eppendorf tips yellow and blue, cuvettes for spectrophotometer, samples cups, Rod to detach clot, disposable forceps,Disposable plastic tubes, winged stoppers for tubes diam. 12mm e 16mm, Test tube with granules and clot activator, vacuum test tube, SEDIPLAST system, micro test tubes, Slides Mailer, "TESTSIMPLETS" slides, rack for test tubes, rack for micro test tubes, CELL-VUE Disposable counting chambers, Butterfly needles, Man's and woman's urinals, bed pan, Bottles for urine collection.

SYNTESYS

SYNTESYS S.A.S. DI RINALDO R. & C.
VIA G. GALILEI 10/3
35037 Z.I. SELVE DI TEOLO (PD)
TEL. +39 049 9903866 R.A. FAX +39 049 9903867
COD.FISCALE P.IVA N.REG.IMP. PADOVA 03573950288
E-MAIL INFO@SYNTESYS.IT - WEB WWW.SYNTESYS.IT

Materiale/*Material*

Polipropilene, Polistirolo, Polietilene e Metacrilato/*Polypropylene, Polystyrene, Polyethylene and Methacrylate*

È conforme alle disposizioni della direttiva 98/79/CE concernente i dispositivi medici diagnostici in vitro e recepito in Italia con D.L. del 08/09/2000 n° 332 allegato 1 (requisiti essenziali) ed è fabbricato in accordo ai requisiti di cui all'Allegato III della sopra citata direttiva./*It meets the specifications established by the Italian law n. 332, dated 8th September 2000. The device is made according to the specifications of the III attached of the above-mentioned directive.*

Dichiara inoltre che la documentazione tecnica di supporto alla presente dichiarazione di conformità è conservata presso gli uffici dell'azienda e sarà posta alla disposizione di chi la richiede/*declares that all technical documents attached to this conformity statment are filed in our company and can be consulted by any authorized body on demand.*

Data 01/10/2012

SYNTESYS S.a.s.
Il legale rappresentante
Rinaldo Ruggero

PRODOTTI E STRUMENTAZIONE PER ANALISI DI LABORATORIO - DISPOSABLE LABWARE

REPUBLIKA HRVATSKA
AGENCIJA ZA LIJEKOVE I MEDICINSKE PROIZVODE

REPUBLIC OF CROATIA
AGENCY FOR MEDICINAL PRODUCTS AND MEDICAL DEVICES
Ksaverska c. 4, 10000 ZAGREB, CROATIA
Tel.: ++ 385 1 4884 100, Fax: ++385 1 4884 110
e-mail: halmed@halmed.hr
www.halmed.hr
OIB 37926884937

Klasa: 530-04/16-01/35
Ur. br.: 381-13-07/36-16-02
Zagreb, 10.08.2016.

Biognost d.o.o.,
Republika Hrvatska, Zagreb,
Međugorska 59

POTVRDA O SLOBODNOJ PRODAJI
(CERTIFICATE OF FREE SALE)

Agencija za lijekove i medicinske proizvode Republike Hrvatske ovim putem potvrđuje da niže navedeni medicinski proizvod ispunjava zahtjeve Zakona o medicinskim proizvodima („Narodne novine", br. 76/13.) te Pravilnika o bitnim zahtjevima, razvrstavanju, upisu proizvođača u očevidnik proizvođača, upisu medicinskih proizvoda u očevidnik medicinskih proizvoda te ocjenjivanju sukladnosti medicinskih proizvoda (Narodne novine, br. 84/13.), kojima se prenose direktive o medicinskim proizvodima Europske unije.

The Agency for Medicinal Products and Medical Devices of the Republic of Croatia herby certifies, that medical device listed below, is in the conformity with the Medical Devices Act („Official Gazette", No. 76/13.) Ordinance on Essential Requirements, Classification, Entry into the Register of Manufacturers and Medical Devices and Assessment of Conformity of Medical Devices ("Official Gazette", No. 84/13) transposing the medical devices directives of the European Union.

Medicinski proizvod:
Medical Device:

Reagensi za histopatologiju
Klasa rizika in vitro dijagnostika - ostalo / Risk Class – in vitro diagnostics Others

Proizvođač:
Manufacturer:

Biognost d.o.o.,
Republika Hrvatska,
Zagreb,
Međugorska 59

nalazi se u prometu u Republici Hrvatskoj, te se slobodno izvozi.
is marketed in Republic of Croatia, and is free to export.

REPUBLIKA HRVATSKA - AGENCIJA ZA LIJEKOVE I MEDICINSKE PROIZVODE 2 ZAGREB

Ravnatelj Agencije / *Head of Agency*

Izv. prof. dr. sc. Siniša Tomić

REPUBLICA MOLDOVA, mun. Chi... CONTRACTE ȘI ACHIZIȚII IDNO 1003600052156 SOCIETATEA CU RĂSPUNDERE LIMI...

Upravna pristojba u iznosu od 40,00 kuna po Tar. br. 1 i Tar. br. 4 Tarife upravnih pristojbi Zakona o upravnim pristojbama („Narodne novine“, broj 8/96., 77/96., 95/97., 131/97., 68/98., 66/99., 145/99., 116/00., 163/03., 17/04., 110/04., 141/04., 150/05., 153/05., 129/06., 117/07., 25/08., 60/08., 20/10., 69/10., 126/11., 112/12., 19/13., 80/13., 40/14., 69/14., 87/14., 94/14.) je plaćena.

Dostaviti:
1. Naslovu
2. Pismohrana – ovdje.

BIOGNOST ®
FARMACEUTSKI I DIJAGNOSTIČKI PROIZVODI

BioGnost d.o.o.
Međugorska 59
10040 Zagreb, Hrvatska
MB 3595722 OIB 05273195306

+385 1 2409997
+385 1 2404039
www.biognost.hr
biognost@biognost.hr

Declaration of Conformity Certificate

Izjava o sukladnosti

Certificate No. / broj izjave 0182016-BIOG

BIOGNOST d.o.o.
Međugorska 59
10040 Zagreb, Croatia

ensures and declares with sole responsibility, that following *In Vitro* Diagnostic Medical Devices:
jamčimo i izjavljujemo s potpunom odgovornošću, da naši *In Vitro* dijagnostički medicinski proizvodi:

Laboratory diagnostics and microscopy supplies and reagents
Pribor i sredstva za laboratorijsku dijagnostiku i mikroskopiju

See attached Product List
Popis proizvoda u prilogu

meet the provisions of Council Directive 98/79/EC (IVDD) which apply to us. This declaration is based on approval according to Annex III (excluding III.6) of the Directive.

udovoljavaju svim propisanim zahtjevima Europskog Vijeća - 98/79/EC (IVDD). Ova Izjava temelji se na odobrenju prema Aneksu III (isključujući III.6) direktive.

Signed this day 16 May 2016
Potpisano dana 16. svibnja 2016.

BIOGNOST
BIOGNOST d.o.o., www.biognost.hr
Međugorska 59, 10040 Zagreb, Croatia

.....

Ivan Marchiotti, MD MSc
Director
BIOGNOST LTD.

MANAGEMENT SYSTEM CERTIFICATE

Certificate No:
72014-2010-AQ-HRV-HAA

Initial certification date:
21, January, 2004

Valid:
20, December, 2015 - 19, December, 2018

This is to certify that the management system of

BIOGNOST d.o.o.

Međugorska 59, 10040, Zagreb, Croatia

has been found to conform to the Quality Management System standard:
ISO 9001:2008

This certificate is valid for the following scope:
Development, production and wholesale of in vitro diagnostic reagents and medical products; and wholesale of drugs

Place and date:
Zagreb, 26, November, 2015

17021 · HAA
4075
QMS

For the issuing office:
DNV GL – Business Assurance
Buzinski prilaz 32, 10010, Zagreb, Croatia

Franjo Potak
Management Representative

Lack of fulfillment of conditions as set out in the Certification Agreement may render this Certificate invalid.
ACCREDITED UNIT: Det Norske Veritas Adriatica d.o.o., Buzinski prilaz 32, 10010 Zagreb, Croatia. TEL:+385 1 2499 850, http://assurance.dnvgl.com

GREETMED® **NINGBO GREETMED MEDICAL INSTRUMENTS CO., LTD.**

Add: 18F-3, No.1 Building, Wante Business Centre, Hi-Tech Zone, 315042 Ningbo, PEOPLE'S REPUBLIC OF CHINA

Tel: 0086-574-87739070, 87722370, 87739297, 87711530
Fax: 0086-574-87722360, 87739075
P.C.: 315042

Date of issue: **1st Jan, 2018**

To whom it may concern

CERTIFICATE OF AUTHORIZATION:

Distributorship for products.of Ningbo Greetmed Medical Instruments Co., Ltd.

This is to certify that,

ECOCHIMIE Ltd.
5/1, Cuza Voda str., MD-2060, Kishinau,
Republic of Moldova
Tel.: +373 /22/ 523-432
Fax.: +373 /30/ 555 596
import@ecochimie.md
infoecochimie@gmail.com
www.ecochimie.md

is our authorized distributor for the complete product line of Ningbo Greetmed Medical Instruments Co., Ltd.

This company is able to provide competitive and professional sales information, to take parts in tenders and after-sales service of products of Ningbo Greetmed Medical Instruments Co., Ltd. to their customers in his area and to participate in tenders on behalf of Ningbo Greetmed Medical Instruments Co., Ltd.

President

Ningbo Greetmed Medical Instruments Co., Ltd.
Signature and seal

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 17 02 73283 037

Manufacturer:

Ningbo Greetmed Medical Instruments Co., Ltd.
18F-3, No.1 Building
Wante Business Centre, Hi-Tech Zone
315042 Ningbo
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80
20537 Hamburg
GERMANY

Product Category(ies):

For detailed information please see attachment

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.: SH1729913

Valid from: 2017-08-11
Valid until: 2021-04-17

Date, 2017-08-11

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV®

A1 / 04-11

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate
Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 17 02 73283 037

Facility(ies):

Ningbo Greetmed Medical Instruments Co., Ltd.
18F-3, No.1 Building, Wante Business Centre,
Hi-Tech Zone, 315042 Ningbo, PEOPLE'S
REPUBLIC OF CHINA

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Attachment for Certificate No G2.17.02.73283.037

Supplement 001 dated 2017-08-11

Product Service

For the product(s)/product category (ies):

Tracheal Tubes, Surgical Gloves,
Electronic Sphygmomanometers, Digital Thermometers,
Infra-red Ear Thermometers, Infra-red Forehead Thermometers,
Disposable Infusion Sets, Disposable Syringe Sets,
Disposable Blood Transfusion Sets,
Disposable Scalp Vein Sets, Oxygen Masks, Aerosol Masks,
Nasal Oxygen Cannula, Non-Rebreath Masks,
Disposable Surgical Blades, Sterile Blood Lancets,
Suction Catheters, Feeding Tubes, Stomach Tubes,
Connecting Tubes with Yankauer Handle, Nelaton Catheters,
Reinforced Endotracheal Tubes, Laryngeal Mask,
Mucus Extractor, Wound Drainage Reservoir,
Three-way Stopcocks, Heparin Caps, I.V. Cannula,
Insulin Syringe, Infusion Set with Burette,
Hypodermic Needle, Closed Suction Catheter,
Non-absorbable Surgery Suture, Safety Syringes,
CPR Masks, Venturi Masks, Ultrasonic Nebulizer,
Compressor Nebulizer, Tracheostomy Mask,
Manual Resuscitators, Surgical Scalpel,
Latex Foley Catheter, T-Drainage Tube,
Penrose Tube, Lap Sponges, Insulin Pen Needles,
Electrocardiograph, Transcutaneous Jaundice Detector,
Neonate Bilirubin Phototherapy Equipment,
Lubricating Jelly, Urethral Catheters,
Endotracheal Tube Introducers, Anesthetic Breathing Circuits,
Endotracheal Tubes with Evacuation Lumen,

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Attachment for Certificate No G2.17.02.73283.037

Supplement 001 dated 2017-08-11

Product Service

O2+CO2 Sampling Cannulas, Humidifier Jar,
Mask Nebulizer Container, Auto-disable Syringe,
Anesthesia Mask, Resuscitation Mask,
Nebulizers with Mouth-pieces, Oxygen Connection Tubings,
Nebulizer Set, Three-way Stopcock and Extension Tube,
Dental Needles, Disposable Vacuum Blood Collection System,
Disposable Umbilical Cord Scissors, Blood-Collecting Needles,
Disposable Anesthesia Laryngoscope,
Heat & Moisture Exchanger Filters,
Breathing System Filters, Drainage Tubes,
Screw Cap (Combi Stopper), Enema Set

Munich, MHS-CRT, 2017-08-11

Stefan Preiß
Certification Medical Technology

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV®

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **09 100 90249**

Certificate Holder:

ISOLAB Laborgeräte GmbH
Bahnhofstr. 10
97877 Wertheim
Germany

Scope: Development, manufacture and distribution of Laboratory equipment and chemicals

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2017-12-01 until 2020-11-30.
First certification 1999

2017-10-19

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

DAkkS Deutsche Akkreditierungsstelle D-ZM-16031-01-00

TÜVRheinland®
Precisely Right.

Certificate

kiwa
Partner for progress

İNTERLAB LABORATUAR ÜRÜNLERİ SANAYİ VE TİCARET ANONİM ŞİRKETİ

ÖMERLİ MAH. HADIMKÖY-İSTANBUL YOLU CADDE NO: 189
ARNAVUTKÖY – İSTANBUL – TÜRKİYE

with a scope of

PRODUCTION, SALES AND PROVISION OF TECHNICAL SERVICES FOR STERILE AND NON STERILE LABORATORY MATERIALS MADE OF GLASS AND PLASTICS

Medical devices - Quality management systems - Requirements for regulatory purposes

" Following elements of the standard are excluded "
"7.5.1.2.2" "7.5.3.2.2" "8.2.4.2"

EN ISO 13485:2012

Certificate No	: M 7836
Initial Certification Date	: 02 March 2010
Certification Date	: 23 February 2016
Expiration Date	: 22 February 2019

General Manager

TÜRKAK
Medical Device Q.M.S.
TS EN ISO/IEC 17021
AB-0006-YS

Kiwa Meyer Certification Services Inc.
ITOSB 9. Cadde No. 15 Tepeören - Tuzla İstanbul – Türkiye
Tel: + 90 216 593 25 75 Fax : + 90 216 593 25 74
Web: www.kiwa.com.tr E-mail: posta@meyer.gen.tr

Certificate is valid till expiration date, subject to successful completion of periodical surveillance audits.
Please contact above numbers for detailed information.

Last Modified: 23 February 2016- R 03

ISOLAB Laborgeräte GmbH

DIN EN ISO CERTIFIED 9001

Datum/Date : 30.03.2017

LETTER OF AUTHORIZATION

We, the undersigned Isolab Laborgeräte GmbH, hereby confirm that the company:

S.C.ECOCHIMIE S.R.L.
Str. Cuza Voda, 5/1, of. 403, Chisinau MD-2060,
Republica Moldova

is authorized to offer our products in open procedure for public procurement and tenders.

This authorization is valid until tender contract is fulfilled.

Yours faithfully,
Isolab Laborgeräte GmbH,
Signature and stamp

ISOLAB Laborgeräte GmbH
Bahnhofstraße 10
D-97877 Wertheim
Tel. +49 93 42 91 23 55
Fax +49 93 42 91 23 57
www.isolabgmbh.de

Volumetric Glassware

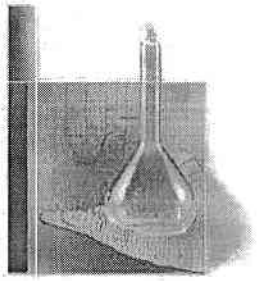
Laboratory Equipment

Liquid Handling

Laboratory Instruments

Certified acc.
DIN EN ISO 9001:2000

Certificate no.
09 100 90249



Address
Isolab Laborgeräte GmbH
Bahnhofstraße 10
D-97877 Wertheim

Telephone
+49 (0)93 42 91 23 55

Facsimile
+49 (0)93 42 91 23 57

E-Mail
sales@isolabgmbh.de

Internet
www.isolabgmbh.de

МиниМед
поставщик лабораторий

241520, г. Брянск, Супонево, ул. Шоссейная, 17 А
Тел. (4832) 92-97-97, 92-24-53, -55, -56, -57, -58, -60, -62
Факс (4832) 92-24-54, 92-24-59, 92-24-61
www.minimed.ru e-mail: info@minimed.ru
Р/с 40702810308000100320 Брянское ОСБ № 8605 г. Брянск
К/с 30101810400000000601 ИНН 3234007127 БИК 041501601
КПП 320701001 ОКПО 29508133

ИНФОРМАЦИОННОЕ ПИСЬМО.

Уважаемые коллеги, доводим до вашего сведения, что
реактив Сульфосалициловая кислота 2-водн., чистая, уп. 1 кг,
не

наименование продукции

входит в перечень продукции, подлежащей обязательной сертификации, утвержденный постановлением Правительства РФ № 982 от 1 декабря 2009 г.

С уважением!
Директор ООО «Минимед» Азбукин В.Р.

ООО «Торговая компания МСД»

105077, г.Москва, Измайловский б-р, д.58
ИНН/КПП 7719808826/771901001, ОГРН 1127746287020, ОКПО 09212267
р/с 40702810300000081583в ВТБ 24 (ЗАО), г. Москва, БИК 044525716, к/с
30101810100000000716
тел. (495) 787-01-37, факс (495)787-52-11, www.mcd-chemicals.ru

Наименование препарата	Сульфосалициловая кислота 2-вод. Sulphosalicylic acid ($C_7H_6O_6S \cdot 2H_2O$)
Анализ выполнен по	ГОСТ 4478-78/изм.1/
Партия	12F0828
Изготовитель	Китай
Дата изготовления	08/2012 г
Вид и тип тары	мешки 25,0 кг
Срок годности	2 года

Показатели качества:

Наименование показателей	Требования ГОСТ «ч»	Результат анализа
Содержание основного вещества, %, н/м	97,5	99,9
Массовая доля нерастворимых в воде веществ, %, н/б	0,010	0,005
Массовая доля остатка после прокаливания, %, н/б	0,02	0,0023
Массовая доля сульфатов (SO_4), %, н/б	1,0	0,2
Массовая доля хлоридов (Cl), %, н/б	0,005	Менее 0,001
Массовая доля железа (Fe), %, н/б	0,0005	Менее 0,0005
Массовая доля тяжелых металлов (Pb), %, н/б	0,0010	Менее 0,0005
Массовая доля салициловой кислоты, %, н/б	0,20	0,03

Заключение: Показатели соответствуют ГОСТу 4478-78/изм.1/ квалификации "ч"

Копия верна

ОБЩЕСТВО С ОГРАНИЧЕННОЙ ОТВЕТСТВЕННОСТЬЮ «ЮНИКЕМ» ДЛЯ ДОКУМЕНТОВ

REPUBLICA MOLDOVA

ООО "МиниМед", 241520, Российская Федерация, Брянская область, Брянский район, с. Супонево, ул. Шоссейная, 17 А

Тел. (4832) 92-97-97, 92-24-52, -53, -55, -56, -57, -58, -60, -61, -62
Многоканальный номер - 8-800-100-48-32
Факс (4832) 92-24-54, 92-24-59, 92-24-61

ИНН 3234007127 www.minimed.ru e-mail: info@minimed.ru

Код ОКП 93 9816

Регистрационное удостоверение
№ ФСР 2007/00154 от 9.10.2007 г.

Паспорт

Набор реагентов для контроля качества предстерилизационной очистки изделий медицинского назначения (Азопирам-МиниМед) ТУ 9398-006-29508133-2007

Серия
Дата изготовления

Срок годности – 12 месяцев с даты изготовления.

1. Назначение

Предназначен для обнаружения остатков крови на изделиях медицинского назначения при контроле качества их предстерилизационной очистки.

2. Технические требования

Наименование показателя	Характеристика и норма	Соответствие ТУ
Внешний вид 1.Амидопирин (реагент 1) 2.Анилин г/хл (реагент 2)	1.Мелкокристаллический порошок белого цвета 2. Мелкокристаллический порошок белого или розоватого цвета	Соответствует
Растворимость реагентов в 95% этиловом спирте при комнатной температуре (18-25°С); мин, не более	5	Соответствует
Чувствительность, разведение крови дистиллированной водой, в соотношении, не более	1:8000	Соответствует
Время появления окрашивания при проведении реакции, сек., не более	60	Соответствует

Состав набора реагентов: 1) реагент №1 (амидопирин)
2) реагент №2 (анилин гидрохлорид)
3) инструкция по применению

Набор рассчитан на проведение 1500 определений при расходе 0,1 мл рабочего реагента на один анализ.

3. Транспортирование и хранение

Транспортирование набора должно проводиться всеми видами крытого транспорта при температуре от 0 до 25°С в соответствии с правилами перевозки грузов, действующими на данном виде транспорта. Хранение набора в упаковке предприятия-изготовителя должно производиться при комнатной температуре (18-25°С) в течение всего срока годности.

4 Гарантии изготовителя

Изготовитель гарантирует соответствие набора требованиям ТУ 9398-006-29508133-2007 при соблюдении потребителем условий транспортирования, хранения и применения в течение всего срока годности.

Начальник ОТК **Захаров А.Н.**

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

от 18 августа 2015 года № РЗН 2015/2981

На медицинское изделие
Стекла для микропрепаратов по ТУ 9464-012-52876859-2014

Настоящее регистрационное удостоверение выдано
Общество с ограниченной ответственностью "МиниМед"
(ООО "МиниМед"), Россия,
241520, Брянская область, Брянский район, с. Супонево, ул. Шоссейная, д. 17А

Производитель
Общество с ограниченной ответственностью "МиниЛаб"
(ООО "МиниЛаб"), Россия,
242600, Брянская область, г. Дятьково, ул. Ленина, д. 182, корп. 1

Место производства медицинского изделия
242600, Брянская область, г. Дятьково, ул. Ленина, д. 182, корп. 1

Номер регистрационного досье **№ РД-5893/48646 от 26.12.2014**

Вид медицинского изделия -

Класс потенциального риска применения медицинского изделия 1

Код Общероссийского классификатора продукции для медицинского изделия 94 6450

Настоящее регистрационное удостоверение имеет приложение на 1 листе

приказом Росздравнадзора от 18 августа 2015 года № 5798
допущено к обращению на территории Российской Федерации.

Врио руководителя Федеральной службы
по надзору в сфере здравоохранения **Д.В. Пархоменко**

0012259

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

ПРИЛОЖЕНИЕ
К РЕГИСТРАЦИОННОМУ УДОСТОВЕРЕНИЮ
НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

от 18 августа 2015 года № РЗН 2015/2981

На медицинское изделие
Стекла для микропрепаратов по ТУ 9464-012-52876859-2014, варианты исполнения:
1. Стекло предметное:
- СП с необработанными краями;
- СП-7102 с необработанными краями;
- СП-7101 со шлифованными краями;
- СП-2 Люкс для растяжки мазков со шлифованными краями и фаской;
- СП-5 с односторонним матированием;
- СО-1 с полосой для записи;
- СО-2 для растяжки мазков со шлифованными краями и фаской;
- СО-3 со шлифованными краями;
- СО-4 со шлифованными краями и полосой для записи;
- СО-5 с односторонним матированием;
- СПО-3 с 3-мя окошками;
- СПО-6 с 6-тью окошками;
- СПО-8 с 8-ми окошками;
- СП с адгезивным покрытием-силан, со шлифованными краями и полосой для записи;
- СП с адгезивным электростатическим покрытием со шлифованными краями и полосой для записи;
- СП-7105 со шлифованными краями и полосой для записи;
- СП-7109 с полированными краями и цветной полосой для записи;
- Стекло для копрограмм;
- СП-7103 с 1-ой лункой;
- СП-7104 с 2-мя лунками;
- СП-7103А с 3-мя лунками.
2. Стекло матовое для замешивания:
- без лунки;
- с 1-й лункой;
- с 2-мя лунками;
- с 3-мя лунками.
3. Стекло покровное.
4. Стекло «часовое».

Врио руководителя Федеральной службы
по надзору в сфере здравоохранения **Д.В. Пархоменко**

0013287

МиниМед®
поставщик лабораторий

ООО "МиниМед", 241520, Российская Федерация, Брянская область, Брянский район, с. Супоново, ул. Шоссейная, 17 А

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Факс (4832) 92-24-54, 92-24-59, 92-24-61

ИНН 3234007127 www.minimed.ru e-mail: info@minimed.ru

Код ОКП 94 6450

Регистрационное удостоверение
№ РЗН 2015/2981 от 18.08.2015

Паспорт

СТЕКЛА ДЛЯ МИКРОПРЕПАРАТОВ ПО ТУ 9464-012-52876859-2014

Стекла для копрограмм

1. Назначение

Предназначены для проведения микроскопического анализа кала (копрограмма) с целью выявления заболеваний органов пищеварения.

2. Основные технические характеристики

1. Изготовлены из прозрачного бесцветного силикатного стекла.
2. Размеры, мм - (52±1,0) × (52±1,0) × (2±0,2); (100±1,0) × (100±1,0) × (2±0,2).
3. Стекла химически устойчивы к действию соляной кислоты и дистиллированной воды.

3. Упаковывание, транспортирование и хранение

Стекла для копрограммы упакованы по 10 штук и 100 штук. Упаковка обеспечивает сохранность изделий при транспортировке. Транспортная упаковка имеет надпись «Хрупкое. Осторожно». Условия транспортирования изделий - по ГОСТ 15150-69 в крытом транспорте любого вида. Условия хранения - по ГОСТ 15150-69.

4. Требования безопасности

При эксплуатации необходимо соблюдать правила безопасности при работе со стеклянными изделиями. Изделия не должны подвергаться резким ударам в процессе эксплуатации.

5. Сведения об утилизации

Утилизация стекол должна осуществляться в соответствии с санитарно-эпидемиологическими правилами и нормами СанПин 2.1.7.2790, класс опасности Б.

6. Гарантии производителя

Производитель: ООО «МиниЛаб», Россия, 242600, Брянская область, г.Дятьково, ул.Ленина, д. 182, корп. 1.
Уполномоченный представитель производителя: ООО «МиниМед», 241520, РФ, Брянская область, Брянский район, с.Супоново, ул. Шоссейная, 17А.
Гарантийный срок эксплуатации — 12 месяцев со дня ввода в эксплуатацию.

7. Свидетельство о приемке

Изделия изготовлены в соответствии с действующей технической документацией и признаны годными для эксплуатации.

Инженер по контролю качества продукции Жарикова О.И.

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

от 07 декабря 2015 года № ФСР 2011/11306

На медицинское изделие
Краситель Азур-Эозин по Романовскому (МиниМед-Р)
по ТУ 9398-003-29508133-2011

Настоящее регистрационное удостоверение выдано
Общество с ограниченной ответственностью "МиниМед"
(ООО "МиниМед"), Россия,
241520, Брянская область, Брянский район, с. Супонево, ул. Шоссейная, д. 17А

Производитель
Общество с ограниченной ответственностью "МиниМед"
(ООО "МиниМед"), Россия,
241520, Брянская область, Брянский район, с. Супонево, ул. Шоссейная, д. 17А

Место производства медицинского изделия
241520, Брянская область. Брянский район, с. Супонево, пер. Комсомольский, д. 7, корп. 2-а

Номер регистрационного досье **№ РД-9275/51846 от 18.11.2015**

Вид медицинского изделия **232730**

Класс потенциального риска применения медицинского изделия **3**

Код Общероссийского классификатора продукции для медицинского изделия **93 9816**

приказом Росздравнадзора от 07 декабря 2015 года № 9111
допущено к обращению на территории Российской Федерации.

Руководитель Федеральной службы
по надзору в сфере здравоохранения **М.А. Мурашко**

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Код ОКП 93 9816

Регистрационное удостоверение
№ ФСР 2011/11306 от 07.12.2015 г.

Паспорт

Краситель Азур-эозин по Романовскому (МиниМед-Р)
ТУ 9398-003-29508133-2011

Серия
Дата изготовления
Размер партии

Срок годности – 1 год с даты изготовления.

1. Назначение

Предназначен для окрашивания форменных элементов крови.

2. Технические требования

Наименование показателя	Норма по ТУ	Результаты испытаний
1. Внешний вид		
1.1. Краситель	Темно-синяя сиропообразная жидкость без нерастворимых примесей	
1.2. Буфер фосфатный	Прозрачная бесцветная жидкость	
2. Плотность раствора красителя при комнатной температуре 20±2°С, г/см^3	1,000 – 1,100	
3. Время наступления окраски мазка (при разведении красителя 1:19), мин, не более	50	
4. Окраска форменных элементов крови	- эритроциты – розовые с серым оттенком, бежево-коричневые; - ядра лейкоцитов – фиолетовые; - цитоплазма лимфоцитов – голубая, серо-голубая; - цитоплазма нейтрофилов – бледно-розовая, серо-розовая; - зернистость нейтрофилов – фиолетовая, красно-фиолетовая; - зернистость эозинофилов – желто-оранжевая, розово-фиолетовая; - зернистость базофилов – фиолетовая; - тромбоциты – розово-фиолетовые, розово-сине-фиолетовые	

3. Транспортирование и хранение

Транспортирование красителя-фиксатора должно проводиться всеми видами крытого транспорта при температуре от 0 до 25°С в соответствии с правилами перевозки грузов, действующими на данном виде транспорта. Краситель следует хранить при температуре от +5° до +25°С в темном месте, вдали от кислот и щелочей в течение всего срока годности.

4. Гарантии изготовителя

Изготовитель гарантирует соответствие красителя азур-эозина по Романовскому требованиям ТУ 9398-003-29508133-2011 при соблюдении потребителем условий транспортирования, хранения и применения в течение всего срока годности.

Начальник ПТО **Захаров А.Н.**